

Remarks

Claims 1, 4, 17 24, 39, 41, 43 and 51-53 are amended herein. Claims 1, 4, 17, 43 and 51 are amended herein to correct a formatting error. Claims 10-11, and 52-53 are amended to clarify that the host cell is "isolated," as requested in the final Office action. Support for the amendment of claim 24 can be found throughout the specification, such as on page 46, line 29 to page 49, line 5. Claims 39 and 41 are amended herein to be directed to compositions including a carrier. Support for the amendment of these claims can be found throughout the specification, such as on page 12, lines 48, line 1 to page 49 line 5 and in the Examples section. Claims 6 and 40 are canceled herein. Applicants expressly reserve the right to prosecute any canceled subject matter in a divisional application.

New claims 54-55 are added herein. Claim 54 is directed to an embodiment originally included in claim 1. Support for new claim 55 can be found throughout the specification, such as on page 25, lines 16-23.

Applicants believe no new matter is added herein. Reconsideration of the subject application is respectfully requested.

Summary of the Telephone Interview

Applicants thank Examiner Goodard for the helpful telephone interview of April 7, 2008, wherein the outstanding rejections were addressed. The Examiner indicated she would review the Decision from the Board for U.S. Application No. 09/763,393 (Exhibit A) and the Pre-Appeal Request for Review and Decision by the Panel for U.S. Application No. 10/495,663 (Exhibit B). Copies of these documents are enclosed herewith. For the Examiner's convenience, a copy of the Notice of Allowance for U.S. Application No. 09/763,393 (Exhibit C) is also enclosed.

Rejections under 35 U.S.C. § 101

Claims 1, 4, 5, 39, 47 and 48 are rejected under 35 U.S.C. § 101 as allegedly there is no specific, substantial or credible utility for the amino acid sequence set forth as SEQ ID NO: 1 (SV-NGEP); at least eight consecutive amino acids of SEQ ID NO: 1 that bind MHC; fusion proteins comprising these

polypeptides or compositions comprising these polypeptides. Applicants respectfully disagree with this rejection.

The Office action acknowledges (see page 4 of the Office action) that the claimed polypeptide is free of the prior art, and that the specification sets forth utilities for these peptides, such as methods of producing an antibody for the detection of prostate tissue, administering the peptides to produce an immune response, and the production of activated cytotoxic T cells. The Office action acknowledges receipt of Das et al., 2007. Das et al. describe the production of antibodies to SV-NGEP using methods described in the specification on page 31, line 28 to page 37, line 29. These antibodies were used to detect SV-NGEP in protein extracts of both normal prostate and prostate cancer. A band of 100 kDA (the predicted size) was detected in cells transfected with a nucleic acid encoding NGEP. In addition, a specific band at the expected size was detected both in normal prostate and prostate cancers (see page 4 and Fig. 2 of Das et al.).

The Office action alleges (1) “Neither the specification or the prior art have produced any evidence that the claimed protein is differentially expressed, hence there is no specific utility for the claimed protein;” (page 8 of the final Office action); (2) there is no evidence that a novel compound (peptide) analogous to other compounds (peptides) should function in any similar manner, as the polypeptides have undetermined function or biological significance (page 5 of the final Office action); and (3) “the post-file [ing] publication does not demonstrate....that utility was well established at the time of filing” and asserts that one of ordinary skill in the art would not have recognized the asserted utilities at the time of filing (pages 8-9 of the final Office action). Each of these assertions addressed below. Applicants request that these remarks be considered in view of the findings by the U.S. PTO in U.S. Application No. 09/763,393, wherein similar utility rejections were reversed by the Board of Appeals, and U.S. Application No. 10/495,663, wherein similar utility rejections were withdrawn by a pre-appeal panel.

(1) Antibodies that bind amino acids 157-933 of SEQ ID NO: 1 are of use to identify metastatic prostate cancer and normal prostate cells

Cancer is known to metastasize; prostate cancer metastasizes to bones, lymph nodes, rectum and bladder (see Wikipedia on Prostate Cancer, discussed in prior response). It is well known that the origin

of a cancer can provide substantial insight into treatment methods.

Thus, expression of a polypeptide including the amino acid sequence set forth as SEQ ID NO: 1 can be used to identify a tumor in a tissue, such as the bone, lymph node, rectum or bladder as being of prostate or uterine origin. Indeed, the specification discloses that antibodies can be used to detect SV-NGEP (SEQ ID NO: 1) expressing cells, to determine whether a subject has metastatic prostate cancer (see page 47, lines 7-8). The specification discloses that SV-NGEP can be used to detect prostate cells or prostate tissue in any biological sample (see the specification, pages 46-49), such as to determine if metastatic prostate cancer is present in a biological sample (see the specification, page 47, lines 1-12). The specification (see page 55, lines 1-24) discloses methods that are of use to detect metastatic prostate cancer at locations in the body other than the prostate by detecting the expression of SV-NGEP (SEQ ID NO: 1). The specification (see page 32, lines 1-13) also describes the production of antibodies using specific antigenic epitopes (of at least six amino acids in length) of SV-NGEP, such as amino acid sequences eight to ten amino acids in length. A reduction to practice, namely the production of an antibody that binds amino acids 875-933 of SEQ ID NO: 1 is disclosed in the examples section (see page 51, line 23 to page 52, line 9). Methods for detecting prostate cancer and cells, such as in biopsies or using immunoassays are described (see for example, page 47 and page 55).

Antibodies are also routinely used in histological analysis, and are often sold as parts of a kit for the detection of cells in any biological sample (see the specification at pages 46-49). The antibodies disclosed herein could be used in routine histological analysis, such as to determine the presence of any prostate cells in a sample. Thus, there is a credible, specific, and substantial utility for the claimed polypeptides in the production of antibodies for the detection of prostate cancer metastasis.

Indeed, the U.S. PTO has confirmed that the production of antibodies that bind a defined tissue type is a specific, substantial and credible use (see Exhibit A). Unless evidence is provided documenting that the production of antibodies specific to an amino acid sequence is incredible (and there is no evidence to support this type of assertion) the Board has concluded that antibodies that bind a polypeptide antigen specifically expressed in prostate cancer to be a credible use. For the Examiner's convenience, a paragraph from page 6 of the Decision is set forth below:

The generation of antibodies specific for a particular polypeptide is well established and well known in the art. *See In re Wands*, 858 F.2d 731, 736 (1988). The Examiner has not provided evidence that the skilled artisan would have found the generation of antibodies specific to SEQ ID NO: 1 using either the entire polypeptide of SEQ ID NO: 1 or the claimed fragments of the polypeptide as the antigen to be incredible, such as to support a conclusion that the claimed polypeptide of SEQ ID NO: 1 and the peptide fragments thereof would lack a patentable utility.

Moreover, post-filing date evidence has been presented documenting the utility of the claimed polypeptides. Das et al. (Cancer Res. 67: 1594-1601, 2007, submitted previously) discloses that there are two forms of NGEF, a short form and a long form (SEQ ID NO: 1 of the present application). Antibodies were produced that specifically bind amino acid sequence set forth as SEQ ID NO: 1. These antibodies were used to detect this protein in extracts of normal prostate and prostate cancers (see Figures 1 and 2). Thus, Das et al. provide evidence documenting that polypeptides comprising the amino acid sequence set forth as SEQ ID NO: 1 continue to be expressed in metastatic prostate cancer.

In addition, Das et al., (poster presentation from the AACR meeting, 2007, Exhibit D) describes the production of a panel of monoclonal and polyclonal antibodies that bind a polypeptide including SEQ ID NO: 1 (SV-NGEP). The antibodies detected the presence of SV-NGEP in extracts of both normal prostate and *prostate cancers* (see Fig. 1E and the table adjacent to Fig. 1). Thus, antibodies can readily be produced to a polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 1, and these antibodies have been used to detect prostate cancer (as well as normal prostate, see below).

It has been clearly documented that polypeptides comprising the amino acid sequence set forth as SEQ ID NO: 1 are expressed in prostate cancer. Data has been presented documenting that antibodies that specifically bind the amino acid sequence set forth as SEQ ID NO: 1 can be obtained, and that these antibodies can be used to detect polypeptides comprising the amino acid sequence set forth as SEQ ID NO: 1 in prostate cancer cells. Thus, a first specific, substantial and credible use has been documented for the claimed polypeptides, namely the detection of metastatic prostate cancer.

Antibodies are also routinely used in histological analysis, and are often sold as parts of a kit for the detection of cells in any biological sample (see the specification at pages 46-49). As documented, proteins comprising the amino acid sequence set forth as SEQ ID NO: 1 can be used to produce antibodies that specifically bind this protein. The specification discloses that these antibodies can be used in routine histological analysis (see pages 40-42), such as to determine the presence of any prostate

cells (from either a tumor or from a normal prostate) in a sample.

The detection of any prostate tissue is a specific, substantial and credible use. Antibodies to prostate cells are used to study the development and maturation of the prostate. This is exemplified in Exhibit E (Renneberg et al., J. Anat. 190: 343-349, 1997), which describes an immunohistochemical study of a prostate membrane specific protein during the development and maturation of the human prostate.

Antibodies that bind normal prostate are available as commercial products. Submitted herewith as Exhibit F are printouts of data sheets for antibodies that are currently being sold (AbCam, Prostate Secretory Protein/PSP antibody, protein produced in prostate, <http://abcom.com/indext.html?datasheet+19070>; Abcam, PATE (prostate and testis expressed gene, <http://biocompare.com/matrixsc/3194/2/6/118846/PATE+...>; Research Diagnostics, Inc, Prostate Specific Antigen (PSA), <http://researchd.com/miscabs/psa.htm>). The number of antibodies that bind antigens expressed in normal prostate cells that are for sale documents that a market demand exists for multiple antibodies that bind antigens expressed in normal prostate, and for methods to detect prostate cells by detecting prostate-specific protein expression. Antibodies that specifically bind SV-NGEP are of use to detect normal prostate cells (see Das et al., Cancer Res. 67: 1594-1601, 2007, previously submitted).

Thus, the assertion that antigens that are expressed in normal cells cannot be of use is not supported by the evidence. Applicants have documented that a protein with the amino acid sequence set forth as SEQ ID NO: 1 can be used to produce antibodies, and that these antibodies specifically bind prostate cells. The Applicants have also demonstrated that expression of protein comprising SEQ ID NO: 1 can be used to identify prostate cells. Methods to detect proteins in normal prostate cells are established in the art, and thus have real-world use and commercial value. Thus, a second specific, substantial and credible use has been demonstrated.

A similar utility rejection was asserted in U.S. Application No. 10/495,663. This application discloses a polypeptide that is expressed in both normal prostate and prostate cancer. The utility rejection was withdrawn in a Pre-Appeal Request for Review and Decision by the Panel for U.S. Application No. 10/495,663.

Reconsideration and withdrawal of the rejection are respectfully requested.

(2) Knowledge of the exact biochemical and/or biological function of the protein is not required for the specified utility

The final Office action alleges that the biochemical function of the protein must be known in order to provide a use for the protein. Applicants respectfully disagree. Uses for the claimed polypeptides, namely in the production of antibodies that can be used to specifically identify prostate cancer and prostate cells has been documented, and is discussed above. One of skill in the art does not need to understand the biochemical or biological function of a protein for the production of antibodies. Sufficient information, namely the amino acid sequence and the location of the extracellular domains of the protein (see the specification Table on page 23) are provided to enable the production of antibodies.

Moreover, MPEP § 2163 states:

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, [>] disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004).

Thus, the structural formula provides sufficient information to identify a biomolecule, such as SV-NGEP. With regard to the present application, the structural formula of the claimed polypeptides is provided, namely the amino acid sequence set forth as SEQ ID NO: 1, the specification provides the sequence, namely the complete amino acid sequence set forth as SEQ ID NO: 1. A polypeptide with this sequence of SEQ ID NO: 1 has a defined length and molecular weight.¹

With regard to polypeptides of 8 to 10 consecutive amino acid of the polypeptide having the sequence set forth as amino acids 157 to 933 of SEQ ID NO: 1, the claimed polypeptides also have a defined length and molecular weight. In addition, these polypeptides have a defined binding specificity and affinity: they specifically bind MHC class I. The specification discloses that peptides of use have specific anchoring residues (see page 25). Computer programs for predicting which polypeptides will bind MHC are known in the art, available on the internet, and described in the specification. Eight

¹ Each amino acid has a known molecular weight. To determine the molecular weight of a polypeptide of 933 amino acids, such as SEQ ID NO: 1, the individual weights of each of the 933 amino acids is added together.

specific examples are provided (see page 25 of the specification, SEQ ID NOs: 3-10). These polypeptides could also be used for the production of antibodies, as the specification describes that any antigenic epitope that includes six consecutive amino acids from amino acids 157 to 933 of SEQ ID NO: 1 are of use for the production of antibodies (see the specification at page 32, lines 7-9). Biological methods to test whether a specific epitope is immunogenic are provided (for example, see page 55, line 25 to page 59, line 15).

Knowledge of the biochemical function of the claimed polypeptides neither adds nor detracts from this use. For example, a determination that amino acids 157-933 of SEQ ID NO: 1 function as a tyrosine kinase (or any other type of enzyme) simply does not affect the utility of the protein for specific identification of prostate cancer or prostate cells. U.S. Application No. 09/763,393 and U.S. Application No. 10/495,663 both claim polypeptides (and polypeptide fragments) that are expressed in prostate cancer. The biochemical function of these peptides is not delineated the specifications for either patent application. Upon review the specification and post-filing date evidence, the U.S. PTO found a specific, substantial and credible utility for the polypeptides claimed in these applications. This is evidenced in the attached Decision from the Board for U.S. Application No. 09/763,393 and the Pre-Appeal Request for Review and the Decision by the Panel and Appeal Brief for U.S. Application No. 10/495,663.

Reconsideration and withdrawal of the rejection are respectfully requested.

(3) Post filing date evidence can be used to support a claimed utility

There are several utilities for the claimed polypeptide asserted in the specification, as discussed above. Moreover, the utility of producing antibodies, and using these antibodies to detect prostate, is well-known in the art. Antibodies that bind normal prostate are available as commercial products (see Exhibit F, discussed above). The specification describes an example in which an antibody that binds amino acids 157-933 of SEQ ID NO: 1 was produced (see the specification at page 51, Example 4). Moreover, post-filing date evidence has been presented documenting that the antibodies were of use to detect normal prostate cells (see Das et al., Cancer Res. 67: 1594-1601, 2007, previously submitted).

The Office action states that the submission of post-filing date evidence cannot be used to support an asserted utility (see page 9 of the Office action). This is simply incorrect. The Federal Circuit and its predecessor have determined that in those cases where an applicant supplied a reasonable evidentiary showing supporting an asserted utility, a 35 U.S.C. 101-based rejection should be reversed

(see, for example, *In re Brana*, 51 F.3d 1560, 34 USPQ 1436 (Fed. Cir. 1995); *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *In re Gaubert*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1975); *In re Gazave*, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961), and MPEP 2107.03 (III). Thus, these decisions make clear that post-filing evidentiary showing can be used to support the utility of an invention.

In the present application, the Applicants believe that any assertion of the lack of usefulness of the claimed peptides based the prior art cited in the Office action is rendered moot by the documentation of the specific, substantial and credible use of the claimed polypeptides to detect prostate cancer an normal prostate cells.

Reconsideration and withdrawal of this rejection is also respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-5, 26-30, 39, and 47-48 were rejected as allegedly not being enabled by the specification. The Office action alleges that since the claimed invention is not supported by a specific asserted utility or a well established utility, that one of skill in the art simply could not know how to use the claimed invention. Applicants respectfully disagree.

The Office action alleges that since there is no utility for the claimed polypeptides, it is impossible for one of skill in the art to make or use the claimed polypeptides. However, this assertion is incorrect; there is a specific, credible and substantial utility for the claimed polypeptides, as documented above. As all the arguments presented in the Office action hinge on the lack of utility for the claimed polypeptides, the rejection under 35 U.S.C. § 112, first paragraph should also be withdrawn.

In addition, the *production of polypeptides is routine for a skilled molecular biologist, and is described in the specification as filed* (see, for example, pages 21-31). Methods of detecting prostate tissue and prostate cancer are described in the specification as filed (see pages 46-49).

Once a polypeptide sequence is known, the production of antibodies is routine for one of skill in the art. The production of an antibody to amino acids 875 to 933 of SEQ ID NO: 1, by immunizing

rabbits and mice is described (see the specification as filed, page 51, lines 26-32) in the Examples section. In order to produce these polyclonal antibodies the animals must have had an immune response to the administered polypeptides. Thus, it is clear that methods for the production of an immune response using the claimed polypeptides is clearly enabled by the specification. Moreover, the antibodies were used in a Western blot to detect the proteins expressed in cell culture (see the specification as filed, page 52, lines 1-7); the results are described in the examples section and shown in Fig. 6. The use of Western blots to detect SV-NGEP (SEQ ID NO: 1) to detect prostate tissue and prostate cancer using tissue from biopsies, autopsies and pathology specimens is also disclosed (see the specification as filed on page 47, lines 1-12).

Das et al. describe the use of exact antibodies disclosed in the specification on page 51 to detect SV-NGEP in human prostate tissue using the Western blotting methods disclosed in the specification on page 52. Thus, Das et al. (2007) presents confirmatory evidence documenting that one of skill in the art, *using the methods described in the specification*, could make and use antibodies which can be used to detect cancer and normal prostate cells using the *exact methods disclosed in the specification*.

It appears that the Examiner is requiring the Applicants to provide evidence that all of the claimed polypeptides were documented to bind MHC at the time the application was filed. However, this is not the proper standard for enablement. MPEP § 2164.02 states:

An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).

Das et al. is a publication of the work of the inventors, Drs. Pastan, Bera and Lee (who are co-authors of Das et al., 2007), simply published after the filing date of the present application. This post-filing date evidence supports the specific, substantial and credible utility of the claimed invention, and further provides evidence that the specification fully enables the claimed polypeptides, and methods for using these polypeptides to produce an immune response.

Submitted herewith as Exhibit G is Iavrone et al. (Mol. Cancer. Therapeutics 1: 392-395, 2002). Iavrone et al. describes PAGE4, a protein that is expressed in normal prostate and prostate cancer. Although PAGE4 is an entirely different protein from SV-NGEP, this publication demonstrates that the

synthesis of peptides, the production of antibodies, and the detection of proteins (such as by using Western Blot) were well-known in the art at the time the application was filed. Thus, this evidence supports the assertion that the specification would be enabling for one of skill in the art to make and use the claimed polypeptides.

Given the high level of one of skill in the art, the detailed guidance provided in the specification, and the documentation of reduction to practice, it is clear that the claimed polypeptides and methods are fully enabled. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 6 and 40 are rejected under 35 U.S.C. § 112, first paragraph as allegedly there is insufficient written description for these claims. Applicants respectfully disagree with this rejection. However, solely to advance prosecution, claims 6 and 40 are canceled herein.

Claims 6 and 49-51 are rejected under 35 U.S.C. § 112, first paragraph as allegedly polynucleotides encoding a polypeptide comprising or consisting of eight consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1 that bind an MHC molecule are not enabled by the specification. Claim 6 is canceled herein, rendering the rejection moot as applied to this claim. Applicants respectfully disagree with this rejection as applied to claims 49-51, which are directed to a polynucleotide consisting of a polypeptide comprising or consisting of eight consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1 that bind an MHC molecule.

The Office action states that polynucleotides encoding SEQ ID NO: 1 are fully enabled by the specification. Applicants submit that polynucleotides encoding a polypeptide consisting of eight to ten consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1 that bind MHC are also enabled by the specification. Each of the Wands factors is addressed below:

(1) The quantity of experimentation required:

The amino acid sequence of SV-NGEP is set forth as SEQ ID NO: 1. A nucleotide sequence encoding SEQ ID NO: 1, namely SEQ ID NO: 2 is also provided. The specification discloses specific regions of the SEQ ID NO: 1 that are of primary interest. For example, specific regions of the cell

surface region of SV-NGEP (amino acids 369-421 of SEQ ID NO: 1), amino acids 525-543 of SEQ ID NO: 1, amino acids 610-714 of SEQ ID NO: 1, or amino acids 785-933 of SEQ ID NO: 1, and amino acids 875-933 of SEQ ID NO: 1 (see page 24, lines 15-21). The specification describes the presentation of peptides on MHC, and discloses that peptides with specific anchoring residues are of use (see page 25, lines 3-11). Programs are available on the internet that can identify polypeptides of 8 to 10 amino acids that bind MHC; a specific program is identified in the specification (Bioinformatics and Molecular Analysis Section-BIMAS, see page 25, lines 13-15). In addition, eight specific 9-mers are set forth in the specification that bind MHC (SEQ ID NOs: 3-10, see page 25, lines 16-23). Once an amino acid sequence is identified, it is trivial for one of skill in the art to look at SEQ ID NO: 2 and determine the nucleotide sequence that encodes the desired polypeptide. Thus, minimal (if any) experimentation is required to obtain the claimed nucleotide sequences.

(2) The amount of direction provided:

As discussed above, there is ample guidance provided in the specification. The specification discloses SEQ ID NO: 1 (the amino acid sequence), the localization of the regions of the SEQ ID NO: 1 (see the table on page 23), and a nucleotide sequence encoding SEQ ID NO: 1, namely SEQ ID NO: 2. The specification discloses that specific regions of the cell surface region of SV-NGEP that are of use, such as amino acids 369-421 of SEQ ID NO: 1, amino acids 525-543 of SEQ ID NO: 1, amino acids 610-714 of SEQ ID NO: 1, or amino acids 785-933 of SEQ ID NO: 1, and amino acids 875-933 of SEQ ID NO: 1 (see page 24, lines 15-21). The specification describes the presentation of peptides on MHC, and describes the characteristic of a peptide that binds MHC, such as the presence of anchoring residues (see page 25, lines 3-11). A program that can identify polypeptides of 8 to 10 amino acids that bind MHC is identified in the specification (Bioinformatics and Molecular Analysis Section-BIMAS, see page 25, lines 13-15). In addition, eight specific 9-mers are set forth in the specification that bind MHC (SEQ ID NOs: 3-10, see page 25, lines 16-23). A complete nucleotide sequence (SEQ ID NO: 2) encoding SEQ ID NO: 1 is provided. Thus, there is a considerable amount of direction provided.

(3) The presence or absence of working examples:

Eight polypeptides are set forth that bind HLA2-01 (SEQ ID NOs: 3-10, see the specification at page 25, lines 16-23). The nucleotide sequence encoding these polypeptides can readily be determined by identifying the corresponding nucleotide sequences of SEQ ID NO: 2. Thus there are several working examples provided.

(4) The nature of the invention:

The nature of the invention is polynucleotide sequences, which are routinely produced by chemical synthesis or molecular cloning methods.

(5) The state of the prior art:

Molecular cloning techniques are well known in the art. Computer programs to select polypeptides that bind MHC are known and were available on the internet when the present application was filed (see the specification, page 25, lines 13-13 and Exhibit H, a print-out from the BIMAS prediction program citing to Parker et al., J. Immunol. 152: 163, 1994). The synthesis of short nucleotide sequences is routine and automated.

(6) The relative level of those of skill in the art:

The level of skill of a molecular biologist is very high.

(7) The predictability or unpredictability of the art:

As noted above, computer programs to select polypeptides that bind MHC are known and were available on the internet when the present application was filed. Indeed, the Office action confirms that peptides can be identified from SEQ ID NO: 1 using known computer programs (see the Office action, page 24, point 3). Once a polypeptide sequence is identified, the synthesis of short nucleotide sequences encoding that polypeptide is routine and automated.

(8) The breadth of the claims:

The claims are limited to nucleotide sequences encoding a polypeptide consisting of eight to ten consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1 that bind MHC. Thus, the claims are directed to a limited number of defined polynucleotides.

The Office action states that the claimed polynucleotides and polypeptides are novel, and confirms that SEQ ID NO: 1 is novel. However, just because something is new, such as an amino acid sequence, does not mean that one of skill in the art would not know how to use these novel polypeptides, as asserted in the final Office action (see page 21 of the final Office action). The specification provides more than ample guidance on the use of these polypeptides, both for the production of antibodies to detect prostate cells and cancer, and for the production of an immune response to prostate cancer. The prior art clearly enables computer programs that select peptides that bind MHC, and clearly enables the synthesis of short peptide sequences. Thus, in view of guidance provided by the specification with regard to (1) the full length sequence, (2) the specific regions of SEQ ID NO: 1 that are of interest, (3) the selection of peptides that bind MHC, and (4) the specific examples (SEQ ID NOs: 3-10), and in view of the ample methodologies for the production of polynucleotides known and available in the prior art, Applicants submit that claims 49-51 are fully enabled by the specification.

The Office action further alleges that because the claimed polypeptides have no utility, polynucleotides encoding these polypeptides simply cannot be enabled. As discussed above in detail, the rejection asserted under 35 U.S.C. § 101 should be withdrawn. As there is a specific, substantial and credible utility for the claimed polypeptides, Applicants submit that the rejection of claims 49-51 under 35 U.S.C. § 112, first paragraph should also be withdrawn.

Claims 10, 11, 40, 52 and 53 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled by the specification (see point 12, pages 26-29 of the Office action). Applicants respectfully disagree with these rejections.

However, the claims 10-11 and 52-53 are amended herein to recite that the host cell is “isolated” as suggested in the Office action on page 29. In addition, claim 40 is amended herein to delete “therapeutically effective amount” and thereby be directed to compositions includes the polynucleotide in a carrier, as suggested in the final Office action. Applicants submit that the claim amendments render the rejections moot.

Claims 24 and 25 are rejected under U.S.C. § 112, first paragraph, as allegedly not being enabled by the specification. Applicants respectfully disagree with this rejection as applied to the claims as amended.

Claim 24 is amended herein to be directed to methods for detecting either prostate cancer or prostate tissue. The Office action acknowledges that the specification discloses that a polynucleotide encoding SEQ ID NO: 1, such as SEQ ID NO: 2, is uniquely expressed in normal prostate and prostate cancer (see page 31 of the final Office action). The claims as amended do not require that prostate cancer be distinguished from normal prostate. Methods for detecting prostate cells, prostate tissue and prostate cancer are disclosed in the specification on page 46, line 29 to page 49, line 5. Applicants submit that claims 24-25 as amended are fully enabled by the specification.

Conclusion

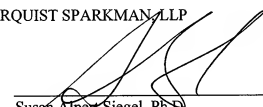
Applicants believe the present application is ready for allowance, which action is requested. If any issues remain, Examiner Goddard is formally requested to contact the undersigned prior to issuance of the next Office Action in order to arrange a telephonic interview, as it is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP § 713.01, which indicates that an interview may be arranged in advance by a written request.

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